

IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

IN RE CASSAVA SCIENCES, INC.
SECURITIES LITIGATION

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Master File No. 1:21-cv-00751-DAE

CLASS ACTION

This Document Relates To:

ALL ACTIONS.

**REPLY IN SUPPORT OF MOTION TO DISMISS PLAINTIFFS' CONSOLIDATED
COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS**

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I. INTRODUCTION

The PSLRA requires that Plaintiffs’ securities fraud claims be dismissed because they are not supported by allegations of fact.¹ To the contrary, the third-party sources for Plaintiffs’ claims readily admit that their accusations of data manipulation are based solely on their *opinion* or *belief* that Cassava’s scientific data *may have been* manipulated. Indeed, in a recent filing, the authors of the Citizen Petitions that form the basis of this lawsuit, David Bredt and Geoffrey Pitt, insisted that the Petitions do “not declare there to have been falsified data,” but offer only the “opinion” that there was “*possible* data manipulation.”² Ex. 10 at 15.³ The authors also do not assert that their Petitions offer statements of fact, but rather a “competing interpretation” of data and issues of “scientific debate.” *Id.* at 1. Accordingly, Plaintiffs cannot rely on the Petitions to plead securities fraud.

In any event, while Plaintiffs claim that Defendants’ challenged statements were misleading because they omitted to disclose data manipulation, there is no duty to disclose, or publicly confess, unadjudicated alleged wrongdoing. Under controlling Fifth Circuit precedent interpreting the PSLRA, unsubstantiated and unadjudicated opinions like those that form the basis of Plaintiffs’ claims cannot be used to plead securities fraud. Put simply, there can be no actionable omission of any alleged “data manipulation” without factual allegations establishing that manipulation did, *in fact*, occur. No such allegations exist here. Plaintiffs simply copy and paste unverified opinion statements from third parties who profited immensely from making those

¹ All abbreviations and short names are taken from Defendants’ Motion to Dismiss Plaintiffs’ Complaint for Violations of the Federal Securities Laws (the “Motion” or “Mot.”).

² Unless otherwise noted, all emphases are added, and all internal quotation marks, brackets, and citations are omitted.

³ On a motion to dismiss, the Court may take judicial notice of documents publicly filed in separate legal proceedings as “matters of public record.” *Davis v. Bayless*, 70 F.3d 367, 372 & n.3 (5th Cir. 1995).

statements. As a matter of law, beliefs and “opinions cannot substitute for facts under the PSLRA.” *Fin. Acquisition Partners LP v. Blackwell*, 440 F.3d 278, 286 (5th Cir. 2006).

Defendants also did not sell any of their Cassava stock at allegedly inflated prices and otherwise had no apparent motive to commit the purported fraud. Thus, to plead the requisite “strong inference” of scienter, Plaintiffs are left arguing that Defendants “must have” known (or were severely reckless in not knowing) that the challenged statements were false and misleading because the alleged data manipulation was purportedly “obvious.” But because Plaintiffs do not allege facts to show that data manipulation *actually* occurred, they fail to adequately plead that Defendants’ statements were false or misleading, let alone so obviously false or misleading that Defendants “must have” acted with fraudulent intent.

Finally, Plaintiffs cannot state a securities fraud claim absent a showing of loss causation, and there are no factual allegations to show that the purported “truth”—that Cassava manipulated its data—was ever revealed to the market. Plaintiffs’ “corrective disclosures” simply repeat the initial Citizen Petition’s opinions and unsubstantiated accusations, and so were not “corrective.”

For these reasons and as further explained below, the Complaint should be dismissed.

II. ARGUMENT

A. The Complaint Does Not Plead An Actionable Misstatement Or Omission

The Complaint alleges nothing more than unsubstantiated accusations and opinions of third parties to conclude that Defendants’ statements must have been false when made. Because “[m]ere conclusory statements are insufficient to defeat dismissal under the PSLRA’s heightened-pleading requirements,” and “opinions cannot substitute for facts under the PSLRA,” *Blackwell*, 440 F.3d at 286, 289, Plaintiffs’ claims must be dismissed. Plaintiffs’ opposition to the Motion (“Opposition” or “Opp.”) offers nothing that would change that conclusion.

1. The Citizen Petitions’ Unsubstantiated Claims Cannot Be Used To Establish An Actionable Omission

Plaintiffs’ core allegation is that Defendants’ statements about Cassava’s scientific data were misleading because they omitted to disclose that Defendants had “manipulated [the] data.” Opp. at 14; CC ¶¶ 287. There is, however, no duty under the federal securities laws to disclose unadjudicated, uncharged wrongdoing, *see* Mot. at 14 (citing, *inter alia*, *Parker v. Hyperdynamics Corp.*, 126 F. Supp. 3d 830, 843 (S.D. Tex. 2015)), and thus Defendants’ purported failure to confess to Plaintiffs’ accusations does not give rise to liability.⁴ Plaintiffs concede, as they must, that silence cannot be misleading absent a duty to disclose. *See* Opp. at 17 (citing *Menaldi v. Och-Ziff Cap. Mgmt. Grp. LLC*, 164 F. Supp. 3d 568, 580 (S.D.N.Y. 2016) (“[c]orporations do not . . . have a duty to disclose uncharged, unadjudicated wrongdoing”)).

Nevertheless, Plaintiffs argue that when Defendants chose to speak publicly about Cassava’s scientific data, they had “a duty to tell the whole truth,” including that the data had purportedly been manipulated. *Id.* at 14. That argument is meritless because the Complaint does not allege any facts to establish that data manipulation actually occurred. *See Menaldi*, 164 F. Supp. 3d at 578 (“If the complaint fails to allege facts which would establish [wrongdoing], then the securities law claims premised on the *nondisclosure* of the alleged [wrongdoing] are fatally flawed.”). In stark contrast to the cases cited in the Opposition (at 14, 17), the Complaint does not allege facts to show, for example, that Defendants made “admissions of wrongdoing,” *see In re ArthroCare Corp. Sec. Litig.*, 726 F. Supp. 2d 696, 702 (W.D. Tex. 2010), or settled claims of wrongdoing, *see In re El Paso Elec. Co. Sec. Litig.*, 2004 WL 377555, at *2 (W.D. Tex. Feb. 23,

⁴ The Opposition claims that it “appears” that the National Institute of Health (“NIH”) has “undertaken some level of adjudication against Cassava” because “Cassava [can] no longer obtain funding from the NIH.” Opp. at 15 n.5. The document Plaintiffs cite for that proposition does not state the NIH “undertook an adjudication against Cassava,” and indeed the NIH has not.

2004); *Bach v. Amedisys, Inc.*, 2016 WL 4443177, at *7 (M.D. La. Aug. 19, 2016). Nor are there allegations to show that Cassava was informed by the FDA (or any other government agency) that its data contained errors such that it gave rise to a duty to disclose. *See* Opp. at 14 (citing *Frater v. Hemispherx Biopharma, Inc.*, 996 F. Supp. 2d 335, 346 (E.D. Pa. 2014) (“When the FDA tells a company about problems with a product, and the company nonetheless continues to make confident predictions about a product, courts have inferred . . . falsity.”)).⁵

In fact, as the Complaint admits, the FDA here ***denied*** the Citizen Petitions’ request to take action against Cassava because the Petitions did not “purport to set forth all the relevant factual information” required to determine if data manipulation occurred. Mot., Ex. 4 at 2 (noting that the “Petitions implicitly acknowledge” that a finding of Cassava’s wrongdoing would “necessarily require fact finding beyond what is presented” in the Petitions). The FDA further agreed that the Company could move forward with its Phase 3 clinical studies. *See* CC ¶¶ 297, 411.⁶

Plaintiffs insist that the Citizen Petitions’ accusations by themselves are enough to establish “specific and widespread instances of data manipulation” that triggered a disclosure obligation. *See* Opp. at 15. But the Citizen Petitions do not allege ***facts*** to show data was actually manipulated, or to show any Defendant did anything wrong. Indeed, the authors of the Petitions themselves have stated that their Petitions do “not make a definitive pronouncement of misconduct or manipulation,” but merely offer the authors’ “***opinion*** that [the purported] anomalies suggest possible data manipulation.” Ex. 10 at 15-16. The authors have further stated that they purposefully used “cautionary language” to indicate that they were offering only their opinion, *id.*

⁵ *See also* *Busic v. Orphazyme A/S*, 2022 WL 3299843, at *17 (N.D. Ill. Aug. 11, 2022) (distinguishing *Frater* because the company in *Frater* received a “complete response letter” from the FDA, which “falls much closer to a ‘final determination’ end of the spectrum of FDA action” and thus gives rise to “an obligation to disclose the details”).

⁶ Plaintiffs’ falsity discussion also cites *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 703-04 (9th Cir. 2016), *see* Opp. at 13, but that decision does not address falsity.

at 16, and that they merely assert that Cassava’s data “*suggests* . . . data manipulation” and has the “*hallmarks* of manipulation” with “*apparent* falsifications” that were “*seemingly* intentional,” *see, e.g.*, CC ¶¶ 105, 107, 109, 120, 146, 149, 172, 176, 192, 193, 199, 227. Plaintiffs here argue that those purported opinions are “corroborated” by other alleged experts, but they too offer nothing more than their own “*belie[f]* . . . that there was some manipulation,” and their own “*conclu[sion]* that [certain] instances of alleged manipulation” occurred because, for example, certain images “*appear* to look identical.” *See id.* ¶¶ 137, 140, 150, 156, 163, 170.⁷

In the Fifth Circuit, those sorts of “opinions cannot substitute for facts under the PSLRA,” *Blackwell*, 440 F.3d at 286, and cannot be used to state a claim for securities fraud, *see also In re KBR, Inc. Sec. Litig.*, 2018 WL 4208681, at *3 (S.D. Tex. Aug. 31, 2018) (“Allowing shareholders to sue based on conclusory allegations that a company has engaged in widespread [mis]conduct without adequately pleading facts that demonstrate [that] conduct would just allow strike suits by another name.”). Plaintiffs cite a California district court decision to argue that an “analyst report offering opinions” is enough to form the basis for a claim, *see Opp.* at 15-16, but the case they cite, *In re QuantumScape Sec. Class Action Litig.*, 580 F. Supp. 3d 714 (N.D. Cal. 2022), holds the *opposite*, and recognizes that third-party reports can be used to state a claim only where they are “littered with fact[s]” about the defendants’ alleged testing failures or based on interviews with “employees [who] claim to personally have encountered flaws in [] testing,” such that “[i]nvestors

⁷ Contrary to Plaintiffs’ argument, Defendants do not assert that the Petitions’ allegations must be disregarded because its authors are self-interested short sellers. *See Opp.* at 15. To the contrary, Defendants agree the Court must credit the “*non-conclusory, factual* portions” of Plaintiffs’ sources. *Id.* But Plaintiffs’ sources do not allege non-conclusory facts; they offer only unproven opinions, beliefs and conclusions, which cannot be used to state a claim under the PSLRA.

need not only have relied on the say-so of the short-seller.” *Id.* at 731.⁸ There are no such facts alleged here.

The same analysis applies to Plaintiffs’ claim that Cassava’s Phase 2b and 2a clinical trial results were misstated. *See* Opp. at 19-20. Plaintiffs offer no specific facts to show that the trial results were misstated but instead simply conclude that because the “Citizen Petition questioned the . . . analysis performed” and “expressed major concerns” about it, the results must have been manipulated. CC ¶¶ 241-42, 245. By the same token, Plaintiffs assert that Defendants’ “statements concerning . . . plasma biomarker results from the Company’s Phase 2b trial were false and misleading,” Opp. at 19, but only because the Citizen Petition expressed its “*concerns*” regarding purportedly “missing data,” CC ¶ 222. Those conclusory accusations likewise fail to state a claim.

2. Plaintiffs’ Remaining Misstatement Allegations Fail As Well

Plaintiffs’ arguments for why Defendants’ other statements were misleading are equally meritless.⁹ First, Plaintiffs argue that “Defendants’ statements that Cassava’s Phase 2b analysis was conducted by an ‘outside’ lab were false and misleading” because they were performed by Dr. Wang. Opp. at 20. Dr. Wang works in a CUNY lab, one that is plainly external to Cassava. Mot. at 19; *see also* Ex. 11 at 5 (Cassava 8-K Report) (describing Lund University lab as an “outside lab” in SEC filing for the initial Phase 2b results).¹⁰ Plaintiffs argue that the statement was nonetheless misleading because Dr. Wang has an “financial interest” in Cassava, but Defendants did not represent that the “outside lab” was unknown to the Company, and thus there is no material

⁸ Plaintiffs note that they need not cite “Cassava employees with first-hand knowledge of the data manipulations” to state a claim. Opp. at 17. True, but they are required to allege *facts* to establish that data manipulation actually occurred, which they have failed to do. *See* Mot. at 14-15.

⁹ The Opposition does not dispute that Plaintiffs’ allegations regarding Cassava’s scientific advisory board, Mot. at 20 (citing CC ¶¶ 480-82), and Barbier’s statements, *id.* at 21 (citing CC ¶¶ 386-88, 412-13) should be dismissed, and thus concedes that those allegations are not viable.

¹⁰ The Court may take judicial notice of “the contents of . . . public disclosure documents” “filed with the SEC.” *Lovelace v. Software Spectrum Inc.*, 78 F.3d 1015, 1018 n.1 (5th Cir. 1996).

misstatement. *See, e.g., Callinan v. Lexicon Pharms., Inc.*, 479 F. Supp. 3d 379, 406 (S.D. Tex. 2020) (omissions are misleading where “directly contradicted by undisclosed information available to the defendants”).

Second, Plaintiffs argue that Defendants’ statement that “plasma p-tau data from Alzheimer’s patients was generated by [Quanterix]” was “plainly misleading,” Opp. at 9 (citing CC ¶ 317), 21, because Quanterix was “engaged to perform sample testing” of data and did “not interpret the test results or prepare the data charts,” CC ¶ 323. As the Motion explains, Cassava’s and Quanterix’s statements are not inconsistent, as Quanterix plainly could have, and did, generate data for Cassava via sample testing without interpreting results or making charts. Mot. at 19-20.¹¹

Third, Plaintiffs claim that when Cassava disclosed that “government agencies ha[d] asked [it] to provide them with corporate information,” the disclosure was misleading because it failed to offer more details about the agencies’ requests. Opp. at 12. But companies have no legal obligation to disclose the details of government inquiries. Mot. at 20-21; *see also In re KBR*, 2018 WL 4208681, at *8 (“[P]laintiffs at most plead that the defendants disclosed an investigation was ongoing, but refused to provide details. Accordingly, these statements are not actionable.”). This case is *not* like the cases cited in the Opposition, where the defendants affirmatively misrepresented the status or scope of government inquiries. *See* Opp. at 22 (citing *Franchi v. SmileDirectClub, Inc.*, 2022 WL 4594575, at *16-17 (M.D. Tenn. Sept. 30, 2022) (falsity established where the company “selectively disclos[ed] particular regulatory [actions] . . . while failing to disclose others”); *Menaldi*, 164 F. Supp. 3d at 583-84 (“Och-Ziff misled investors by

¹¹ Plaintiffs also insist that Cassava’s claim that the “plasma P-tau181 data point missing from the AAIC poster had only ‘increased by 38%’” was misleading because “the missing data point reflected a 150% increase.” Opp. at 21. But the Complaint does not allege facts to establish the purported 150% increase and rests its claim on nothing more than the unsubstantiated opinions and “concerns” of financially interested third-party sources. *See id.* (citing CC ¶¶ 220, 329).

suggesting that the company was not facing an investigation . . . when, in fact, it was”); *Bond v. Clover Health Invs., Corp.*, 587 F. Supp. 3d 641, 680 (M.D. Tenn. 2022) (disclosure of “routine inquiries” misleading where “significant” DOJ investigation existed)).¹²

B. Plaintiffs Fail To Adequately Plead Scienter

The Complaint also does not allege facts giving rise to a “*strong inference* that a[ny] defendant acted with scienter.” Mot. at 22 (citing *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 313 (2007)). In response, Plaintiffs argue that Defendants were motivated to commit fraud by their bonus plan and stock offerings; Defendants’ knowledge or reckless disregard of the fraud can be inferred from their positions at Cassava or their public statements; and Defendants’ “other behavior exhibit[ed] fraudulent intent.” See Opp. at 23-32. These arguments lack merit.

1. Plaintiffs’ Motive Allegations Do Not Create An Inference Of Scienter

Plaintiffs argue that “Cassava’s bonus plan and offerings incentivized Defendants to commit fraud.” Opp. at 29; CC ¶¶ 465-74. But under Fifth Circuit law, allegations “that the defendants were motivated to commit fraud by the need to raise capital [or] the desire for enhanced incentive compensation” are “insufficient to support an inference of scienter” because, “were the opposite true, the executives of virtually every corporation . . . would be subject to fraud allegations.” *Abrams v. Baker Hughes Inc.*, 292 F.3d 424, 434 (5th Cir. 2002); see also *Plaisance v. Schiller*, 2019 WL 1205628, at *21 (S.D. Tex. Mar. 14, 2019) (“[S]cienter . . . may not be based solely on motives universal to all [] executives such as the desire to maintain a high stock price.”).

Plaintiffs also argue that the timing and amount of Defendants’ incentive compensation,

¹² Plaintiffs argue that Cassava’s disclosures of the inquiries were affirmatively misleading because they claimed that Cassava could not predict the impact of the inquiries, when in fact they were already then experiencing an impact, in that NIH funding was no longer available. See Opp. at 22. But there are no allegations to show that NIH funding was unavailable at the time of the alleged misstatement, let alone that the NIH curtailed funding because of the government inquiries.

which was benchmarked to Cassava’s stock performance, constituted “nefarious circumstances,” Opp. at 29, but Plaintiffs do not allege that Defendants ever actually *received* any bonuses, *see* CC ¶¶ 98-104. “Absent an allegation that the defendants profited from the inflated stock value . . . such allegations fail.” *Abrams*, 292 F.3d at 434.¹³ As alleged, Cassava’s executive bonuses would only be paid “provided that the Company has sufficient funds to pay them,” CC ¶ 103, and with only \$25 million in cash at the time that the bonus plan was approved, *id.* ¶ 470, the likelihood that Defendants would receive nearly \$200 million in bonuses is too small to “creat[e] *any* inference of scienter, much less a strong one.” *See Mun. Emps.’ Ret. Sys. of Mich. v. Pier 1 Imports, Inc.*, 935 F.3d 424, 431 (5th Cir. 2019) (“[B]ecause the likelihood that [defendants] would actually receive these high-level bonuses was quite small, *Barrie* does not apply here.”); *see also* Mot. at 26 n.25. In fact, as of Cassava’s most recent quarterly filing on November 7, 2022, “[n]o actual cash payments were authorized or made to participants under the [Cash Incentive Bonus] Plan,” Ex. 12 at 33;¹⁴ *see Elec. Workers’ Pension Fund, Loc. 103 v. Six Flags Ent. Corp.*, 524 F. Supp. 3d 501, 534 (N.D. Tex. 2021) (that “Defendants were never paid the bonuses” cuts against motive inference). Plainly, there was no short-term “cash grab” here, as Plaintiffs argue, *see* Opp. at 30; rather, Defendants remain invested in the legitimate, long-term success of Cassava.

Plaintiffs’ theory that Defendants were motivated to commit fraud to “obtain much needed operating capital,” Opp. at 30-31, fares no better. “[A] plaintiff’s simple reference to ‘badly needed’ or otherwise ‘critical’ financing [does not] warrant[] a strong inference of scienter,”

¹³ Plaintiffs’ out-of-circuit cases are similarly distinguishable. *See* Opp. at 29-30. In *Evanston Police Pension Fund v. McKesson Corp.*, 411 F. Supp. 3d 580 (N.D. Cal. 2019), the plaintiffs alleged “precise amounts each executive *received* in base salary, stock award, and cash awards for each year.” *Id.* at 603. In *Frater*, “each [defendant] personally *received* a bonus” tied to a stock offering, 996 F. Supp. 2d at 343. And *Stone v. Life Partners Holdings, Inc.*, 26 F. Supp. 3d 575 (W.D. Tex. 2014) concerned, unlike here, “unusual or suspicious insider stock sales.” *Id.* at 606.

¹⁴ This judicially noticeable fact, *see supra* n.10, also belies Plaintiffs’ suggestion that Cassava’s capital raise was used to “fill the Company’s bonus pool,” Opp. at 7.

especially where, as here, the stock offering was not alleged to be the “only means of potential financing,” *In re Baker Hughes Sec. Litig.*, 136 F. Supp. 2d 630, 643-44 (S.D. Tex. 2001), *aff’d*, 292 F.3d 424 (5th Cir. 2002); *see* CC ¶ 471 (“I don’t believe raising the money will be an issue”).

More importantly, Plaintiffs acknowledge that Cassava specifically used its capital raises “to fund [simufilam’s] Phase 3 program.” CC ¶ 471. “Courts have repeatedly rejected the inference that a company would continue to invest in a therapy when it supposedly knows it does not work.” *Shash v. Biogen Inc.*, 2022 WL 4134479, at *17 (D. Mass. Sept. 12, 2022) (collecting cases).¹⁵ The fact that “Defendants invested significant resources in [a product’s] development[] indicat[ed a] genuine belief that the drug would receive FDA approval and be successfully marketed.” *Callinan*, 479 F. Supp. 3d at 437.¹⁶

Finally, Plaintiffs’ claim that Defendants sought to personally enrich themselves through their fraud is directly rebutted by Defendants’ lack of stock sales during relevant period, which resulted in significant class period losses for each of the Defendants. *See* Mot. at 25 (citing *Rosenzweig v. Azurix Corp.*, 332 F.3d 854, 867 (5th Cir. 2003) (lack of insider sales “call[s] into question the alleged motive to artificially inflate the stock price”)).

¹⁵ *See also Cozzarelli v. Inspire Pharms. Inc.*, 549 F.3d 618, 627 (4th Cir. 2008) (“It is improbable that [defendant] would stake its existence on a drug and a clinical trial that the company thought was doomed to failure.”); *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 170 (3d Cir. 2014) (“[I]nitiation of Phase 3 cost millions of dollars and required FDA approval, rendering it improbable that defendants would have continued if they did not believe their interpretation of the interim results or if they thought the drug a complete failure.”).

¹⁶ The fact that Cassava used the money it raised to fund simufilam’s Phase 3 trials distinguishes this case from Plaintiffs’ authorities, which involved companies that sought capital “to maintain operations while . . . [an]other late-stage drug candidate advanced towards FDA-approval,” *Voulgaris v. Array Biopharma Inc.*, 2020 WL 8367829, at *3 (D. Colo. Nov. 24, 2020), to finance a re-do “clinical trial **as the FDA had recommended**,” *Frater*, 996 F. Supp. 2d at 350, or to keep the company a “going concern,” *In re Portal Software, Inc. Sec. Litig.*, 2005 WL 1910923, at *12 (N.D. Cal. Aug. 10, 2005); *see also In re MannKind Sec. Actions*, 835 F. Supp. 2d 797, 813 (C.D. Cal. 2011) (“much-needed operating capital”), *McDermid v. Inovio Pharms., Inc.*, 520 F. Supp. 3d 652, 660 (E.D. Pa. 2021) (“mounting research and development expenses”).

2. Plaintiffs’ Attempt to Rely on the Disfavored “Special Circumstances” Doctrine Fails To Establish A Strong Inference Of Scienter

Lacking particularized allegations to establish Defendants’ scienter, Plaintiffs argue that because Defendants as a group were “in charge of developing the Company’s primary drug candidate,” they “knew or recklessly disregarded the adverse information in simufilam’s Phase 2b and Phase 2a trial results and pre-clinical research.”¹⁷ Opp. at 23 (citing CC ¶¶ 438-45). The PSLRA, however, does not allow “group pleading,” Mot. at 27, and therefore “[a] pleading of scienter may not rest on the inference that defendants must have been aware of the misstatement based on their positions within the company,” *Abrams*, 292 F.3d at 432.

To overcome this pleading deficiency, Plaintiffs attempt to avail themselves of the “special circumstances” exception recognized in *Nathenson v. Zonagen Inc.*, 267 F.3d 400 (5th Cir. 2001).¹⁸ Opp. at 23-27. “The Fifth Circuit and other courts have been reluctant to apply the limited exception recognized in *Nathenson*,” and “only in the ‘rare’ case will a strong inference of scienter be drawn from an officer’s position in a company.” *Carlton v. Cannon*, 184 F. Supp. 3d 428, 478-79 (S.D. Tex. 2016). Here, Plaintiffs cannot begin to establish scienter under the “special circumstances” test because the challenged statements did not display a “readily apparent” falsity,

¹⁷ Plaintiffs do not include Defendant Schoen, Cassava’s CFO, in this group. Opp. at 23-25. Rightfully so, because “[t]here are no allegations that [Schoen], in his role as CFO, developed, oversaw, or managed the [drug trials]; his corporate position provides a weaker basis for inferring scienter as a result.” *Stephens v. Uranium Energy Corp.*, 2016 WL 3855860, at *16 (S.D. Tex. July 15, 2016). In fact, Schoen’s only connection to Plaintiffs’ allegations is his name on Cassava’s SEC filings, but “a basis for scienter beyond signatures on SEC filings” is required. *Izadjoo v. Helix Energy Sols. Grp., Inc.*, 237 F. Supp. 3d 492, 520 (S.D. Tex. 2017).

¹⁸ The exception requires “some combination of four considerations that might tip the scales in favor of an inference of scienter”: (1) a small company where it is more likely executives are familiar with day-to-day operations; (2) a transaction “critical to the company’s continued vitality”; (3) the misrepresented information “would have been readily apparent to the speaker”; and (4) the defendant’s statements “were internally inconsistent with one another.” *Loc. 731 I.B. of T. Excavators & Pavers Pension Tr. Fund v. Diodes, Inc.*, 810 F.3d 951, 959 (5th Cir. 2016).

and there are no “internally inconsistent” statements as between Defendants.

To show that the falsity of the challenged statements was “readily apparent,” the “falsity must be so egregious that [an] intent to deceive or recklessness may be presumed from the face of the statement itself.” *In re BP P.L.C. Sec. Litig.*, 2013 WL 6383968, at *19 (S.D. Tex. Dec. 5, 2013); *see also Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 1001 (9th Cir. 2009) (“readily apparent” where “the falsity is patently obvious”). For the reasons stated above, *supra* at II.A, there is no “egregious” falsity here. Plaintiffs’ falsity allegations are founded entirely on the Citizen Petitions’ (and other third parties’) admitted opinions and beliefs, which cannot be used to establish scienter as a matter of law. *See Budde v. Glob. Power Equip. Grp., Inc.*, 2017 WL 6621540, at *3 (N.D. Tex. Dec. 27, 2017) (“[C]ase law standardly finds that opinions . . . add nothing to scienter analysis.”). Furthermore, third parties’ “scientific debate” with Cassava’s data, *see* Ex. 10 at 1, cannot render that data “egregiously false,” because “[m]edical researchers may well differ with respect to what constitutes acceptable testing procedures, as well as how best to interpret data garnered under various protocols,” *Nathenson*, 267 F.3d at 420. Indeed, if the falsity of the challenged statements was “readily apparent,” presumably the FDA, CUNY, or any of the government entities who have been investigating the Citizen Petitions’ allegations since August of 2021, CC ¶¶ 28, 436, would have reached that conclusion by now, *see id.* ¶¶ 5, 26.¹⁹ But the FDA denied the Citizen Petitions, *see* Mot., Ex. 4, and no other authority has taken action against the Company, *see* Mot. at 7-8, 10; CC ¶¶ 28, 436.²⁰

Plaintiffs also fail to specifically allege that Defendants made “internally inconsistent”

¹⁹ The large majority of scientific journals that reassessed submissions from Cassava and/or Dr. Wang found no evidence of manipulation. *See* Mot. at 8-9.

²⁰ Plaintiffs say that scienter can also be inferred from Defendants “publicly discussing the [allegedly misleading] data at issue,” Opp. at 25-27, but Plaintiffs’ authorities recognize that defendants cannot possess scienter unless adverse contradictory “information was transmitted to”

statements about the legitimacy of simufilam’s trial results. *Cf. Plotkin v. IP Axess Inc.*, 407 F.3d 690, 700 (5th Cir. 2005) (company “referred in inconsistent ways to shipments of its product under the agreement”); *QuantumScape*, 580 F. Supp. 3d at 741 (company inconsistently disclosed that its testing conditions were “uncompromised” and “compromised”). To the contrary, Defendants have unequivocally maintained that the Citizen Petitions’ accusations are false. *See* CC ¶¶ 14, 20, 316-17, 331-33.²¹ While Plaintiffs call these denials reckless, *see* Opp. at 27-28,²² the cases they cite find denials reckless only where companies later **admit** to the wrongdoing.²³ Indeed, “[t]his case is quite unlike most securities fraud cases, which are precipitated when the company announces such revelations as . . . the discovery and correction of material errors or misdeeds. . . . Here, there was no mea culpa from the company in the form of acknowledged wrongdoing.” *Ind. Elec. Workers’ Pension Tr. Fund IBEW v. Shaw Grp., Inc.*, 537 F.3d 527, 535-36 (5th Cir. 2008). The “special circumstances” exception therefore does not apply.

them before they spoke, *see City of Pontiac Gen. Emps.’ Ret. Sys. v. Lockheed Martin Corp.*, 875 F. Supp. 2d 359, 372 (S.D.N.Y. 2012); *Roberti v. OSI Sys., Inc.*, 2015 WL 1985562, at *12 (C.D. Cal. Feb. 27, 2015). That is not alleged to be the case here. *See* Mot. at 28.

²¹ Plaintiffs allege that Defendants intentionally manipulated the data analysis of simufilam. Therefore, immaterial errors to visual displays of the (legitimate) underlying simufilam data, *see* CC ¶¶ 334-35, do not change the scienter analysis, *see Pension Tr. Fund for Operating Eng’rs v. Kohl’s Corp.*, 895 F.3d 933, 939 (7th Cir. 2018) (minor errors not evidence of scienter).

²² Plaintiffs argue that Cassava could not have conducted a reasonable investigation of the Citizen Petition’s accusations in “just a few overnight hours between the petition’s release and Cassava’s statement . . . **without** prior knowledge of the data manipulation.” Opp. at 27. But Plaintiffs overlook the obvious, and more “plausible, nonculpable explanation[],” *Tellabs*, 551 U.S. at 310, that Cassava had longstanding knowledge of the data’s **legitimacy**, and therefore acted diligently, and in a detailed manner, *see* CC ¶¶ 316-17, to correct the Petition’s falsehoods before the Company would be damaged any further.

²³ *Cf. ArthroCare*, 726 F. Supp. 2d at 713 (Defendants denied articles that “alleged in substantial detail many of the fraudulent practices [defendant] later admitted”); *In re Sunbeam Sec. Litig.*, 89 F. Supp. 2d 1326, 1338 (S.D. Fla. 1999) (noting “Sunbeam’s own admission that its financial statements prior to and during the class period were false”); *Bach*, 2016 WL 4443177, at *11 (“Amedisys all-but admitted that it engaged in Medicare fraud[.]”).

3. Plaintiffs' Allegations Do Not Otherwise Create Any Compelling Inferences of Scienter

The remainder of Plaintiffs' allegations regarding "other behavior exhibiting fraudulent intent," Opp. at 23, also fail to create a strong inference of any Defendant's scienter. First, while Plaintiffs claim that Defendants' scienter can be inferred from their use of "doctored images" to try and "cover-up" their fraud, Opp. at 28, there are no facts alleged to show Defendants doctored images, but only more of the Citizens Petitions' "conclusory allegations [and] unwarranted deductions." *Southland Sec. Corp. v. INSpire Ins. Sols., Inc.*, 365 F.3d 353, 361 (5th Cir. 2004). "[S]tacking inference upon inference . . . violates the [PSLRA]'s mandate that the strong inference of scienter be supported by facts, not other inferences." *Maguire Fin., LP v. PowerSecure Int'l, Inc.*, 876 F.3d 541, 548 (4th Cir. 2017). In fact, Cassava's participation in "an independent investigation [from the journals], if anything, supports the opposite inference," *Long Miao v. Fanhua, Inc.*, 442 F. Supp. 3d 774, 808 (S.D.N.Y. 2020), especially given that no journal has found evidence of manipulation and the majority have concluded the opposite, *see* Mot. at 8-10.²⁴

Second, Defendants did not "recklessly fail to disclose Wang's conflict of interest and the scope of the government investigations." Opp. at 31-32. "Absent a duty to disclose, failure to disclose is incapable of raising a strong inference of scienter." *Naglich v. Applied Optoelectronics*, 436 F. Supp. 3d 954, 977 (S.D. Tex. 2020). Regardless, Plaintiffs misstate the severe recklessness standard, which is not that the "undisclosed information" was "obvious," Opp. at 31, but that the "danger of misleading buyers or sellers . . . is so obvious that the defendant must have been aware

²⁴ The theory that "an IP address originating from Cassava's headquarters" edited Wikipedia pages or that Cassava deleted an unrelated link about its Scientific Advisory Board from its website, Opp. at 11, in order to "cover their tracks," *id.* at 28, is plainly "a strained and tenuous inference of [scienter that] is insufficient to satisfy the pleading requirement." *Shaw*, 537 F.3d at 543. And Plaintiffs' argument that Barbier misrepresented the FDA's *publicly available* response letter to the Citizen Petitions in order to *cover up* the fraud is illogical. Opp. at 28-29.

of it.” *Nathenson*, 267 F.3d at 408; *see R2 Invs. LDC v. Phillips*, 401 F.3d 638, 644 (5th Cir. 2005) (“Knowledge of an omission does not itself necessarily raise a strong inference of scienter.”). It is not “obviously misleading” to call Dr. Wang’s lab at CUNY, a separate institution, an “outside” lab, nor was this a break from prior practice, *Opp.* at 32, given that Cassava similarly did not name the lab that conducted the initial Phase 2b biomarker analysis, *Ex. 11* at 5. And Defendants did not “misrepresent their exposure to civil and criminal liability,” *Opp.* at 31-32, as they disclosed the existence of investigations without misrepresenting their scope, *see CC* ¶ 363.²⁵

Third, and finally, an “FDA reprimand for misleading marketing practices” *from 2016*, *see Opp.* at 32 (citing *CC* ¶ 475), is not “a regular pattern of related and repeated conduct,” *In re Enron Corp. Sec., Derivative & ERISA Litig.*, 235 F. Supp. 2d 549, 693 (S.D. Tex. 2002), and a previous securities lawsuit that *settled* can hardly be indicative of scienter, *see Opp.* at 32.

At bottom, Plaintiffs’ allegations do not create an inference of scienter that is “cogent and at least as compelling as any opposing inferences.” *Tellabs*, 551 U.S. at 324. As Plaintiffs would have it, a strong inference of scienter exists because third parties who stood to profit from Cassava’s failure claimed that Cassava’s scientific data was *possibly* manipulated, and because Defendants were eligible for larger bonuses in recent years. But the more compelling inference is one of innocence because there are no factual allegations establishing data manipulation; Defendants held their Cassava stock throughout the relevant period and suffered large personal losses as a result of Cassava’s stock price decline; Defendants caused Cassava to make significant

²⁵ Contrary to the out-of-circuit law cited by Plaintiff (*Opp.* at 32 n.17), Fifth Circuit courts consistently find that “[t]he mere existence of a [government] investigation does not . . . add an inference of scienter.” *Parker*, 126 F. Supp. 3d at 843; *see also In re Key Energy Servs., Inc. Sec. Litig.*, 166 F. Supp. 3d 822, 863 (S.D. Tex. 2016) (“The existence of an investigation alone is not sufficient to give rise to a requisite cogent and compelling inference of scienter.”); *Carlton*, 184 F. Supp. 3d at 480 (“The opposing inferences—for example, that the SEC investigation uncovered no evidence of fraud—are more compelling in the absence of particular [contradictory] facts”).

investments into future trials for simufilam (a product Plaintiffs claim is facially worthless); and Defendants continue to steadfastly maintain their innocence.

C. Plaintiffs Fail To Adequately Plead Loss Causation

To adequately plead loss causation, Plaintiffs were required to identify a “corrective disclosure” revealing the “pertinent truth” allegedly concealed by Defendants, followed by a stock price drop. Mot. at 29; *Parker*, 126 F. Supp. 3d at 841-42.²⁶ But “[s]peculation of wrongdoing,” like that offered by Plaintiffs, “cannot . . . arise to a corrective disclosure,” *Amedisys, Inc.*, 769 F.3d at 322, nor can “conclusory allegations,” *Lormand v. US Unwired, Inc.*, 565 F.3d 228, 263 (5th Cir. 2009).²⁷ Put simply, Plaintiffs cannot establish loss causation for the same reason they cannot establish falsity: their claims are founded purely on purported speculation, opinion and belief, and they cannot cite any *facts*, whether available at the time the challenged statements were made or revealed since, to show that Cassava’s scientific data was in fact manipulated. *See* Mot. at 29-35.

Plaintiffs claim that the initial Citizen Petition was the first “partial disclosure” of the supposed “truth” about Defendants’ alleged data manipulation, Opp. at 33, but the authors of the Petition themselves do “not declare there to have been falsified data,” and offer only the “opinion”

²⁶ The Opposition insinuates that a stock price drop alone is enough to establish loss causation. Opp. at 33. That is wrong. Plaintiffs must allege facts to show “a release of information that reveals . . . *the pertinent truth* that was previously concealed” caused a stock price drop. *Pub. Emps.’ Ret. Sys. of Miss., P. R. Tchrs. Ret. Sys. v. Amedisys, Inc.*, 769 F.3d 313, 322 (5th Cir. 2014). Plaintiffs here fail to show any “truth” was “revealed.”

²⁷ Plaintiffs mischaracterize Defendants’ argument as requiring any corrective disclosure to include a criminal conviction. *See* Opp. at 34. Defendants agree that a corrective disclosure can be premised on an array of *factual* evidence, including the “result of [an] internal investigation,” a “restatement of past financial results,” or first-hand employee knowledge. *Catogas v. Cyberonics, Inc.*, 292 F. App’x 311, 313, 316 (5th Cir. 2008); *see Amedisys*, 769 F.3d at 318 (relying on news article citing employee nurse’s knowledge of questionable billing practices). But as the Fifth Circuit has made clear, purported third-party (expert or otherwise) opinions such as those that Plaintiffs rely on “cannot substitute for facts under the PSLRA.” *Blackwell*, 440 F.3d at 286.

that manipulation *may have* occurred, *see supra* at II.A.1. For this reason, the Citizen Petition itself cannot constitute a “corrective disclosure,” because it does not provide facts to “reveal the truth of the previously misleading statement.” *Archdiocese of Milwaukee Supporting Fund, Inc. v. Halliburton Co.*, 597 F.3d 330, 336-37 (5th Cir. 2010).

Plaintiffs next argue that the alleged partial disclosures following the initial Citizen Petition collectively amount to a corrective disclosure, *see Opp.* at 34, but even when amalgamated, those subsequent disclosures still lack the “*new facts*” that “collectively constitute and culminate in a corrective disclosure that adequately pleads loss causation,” *Amedisys*, 769 F.3d at 324; *see also Emps.’ Ret. Sys. v. Whole Foods Mkt., Inc.*, 905 F.3d 892, 904 (5th Cir. 2018) (“Importantly, the corrective disclosure *must reveal some information not already known to the market*[.]”).²⁸ Rather, as the Motion shows, the alleged subsequent partial disclosures simply repeat and offer further speculative belief about the initial Citizen Petition’s conclusory allegations, and nothing more. *Mot.* at 18-19, 31-35; *see also In re AOL Time Warner, Inc. Sec. Litig.*, 503 F. Supp. 2d 666, 679-80 (S.D.N.Y. 2007) (“[W]hile each of these alleged partial disclosures, which comprise . . . third party comments plucked from over a year’s worth of news, notes some concern about [defendants’] accounting, none of them amount to a corrective disclosure.”). Even the subsequent announcements of government investigations offer no additional factual information such that they could be “corrective.” *See In re Dell, Inc. Sec. Litig.*, 591 F. Supp. 2d 877, 909-10 (W.D. Tex. 2008) (disclosure of a governmental investigation, without “revelation of prior

²⁸ Plaintiffs say that determining whether disclosures contain “new” information is “a dispute of fact” that cannot be resolved at the pleading stage. *Opp.* at 35. Wrong. The Fifth Circuit has routinely determined whether a partial disclosure constitutes new information “as a matter of law” on a motion to dismiss. *See, e.g., Whole Foods*, 905 F.3d at 904 (“plaintiffs do not allege that the defendants revealed any new information”); *Catogas*, 292 F. App’x at 315 (“such news did not reveal anything” that “had not already been disclosed”).

misrepresentations,” does not “constitute a corrective disclosure”).²⁹

Citing to *Amedisys*, Plaintiffs argue that “a short seller report, news article and subsequent announcement of SEC and DOJ investigations, followed by a drop in the company’s stock price, are together sufficient to plead loss causation.” Opp. at 34 (citing *Amedisys*, 769 F.3d at 323-25). But *Amedisys* is distinguishable because the corrective disclosure there included *factual allegations* revealing the “pertinent truth,” including an employee’s first-hand experience with the allegedly improper billing practices. See 769 F.3d at 323-25.³⁰ Here, by contrast, none of the alleged partial disclosures following the initial Citizen Petition revealed that the “truth became known,” because they “d[id] not allege . . . any new information,” *Whole Foods*, 905 F.3d at 904, and instead simply parroted “confirmatory information” identical to what was already known to the market, see *In re Omnicom Grp., Inc. Sec. Litig.*, 597 F.3d 501, 512 (2d Cir. 2010) (“[N]egative characterization[s] of already public information” cannot constitute a corrective disclosure).

III. CONCLUSION

For these reasons, the Complaint should be dismissed with prejudice.

²⁹ Neither the Quanterix August 27, 2021 press release clarifying and confirming Cassava’s public statements, nor Cassava’s September 3, 2021 public statement, which categorically denies the allegations in the Citizen Petitions, reveals any new information showing “the falsity” of Cassava’s prior representations. See *Catogas*, 292 F. App’x at 314-15.

³⁰ Plaintiffs’ cited authorities are all distinguishable on that basis because, unlike here, in those cases the third-party reports were *corroborated by facts*. See Opp. at 34 (citing *Bond*, 587 F. Supp. 3d at 668, 679-80 (report corroborated by testimony of confidential witnesses and defendants’ concessions); *QuantumScape*, 580 F. Supp. 3d at 732 (report credited where it was based on testimony from “nine former employees”); *Franchi*, 2022 WL 4594575, at *20 (factual allegations in a related complaint “were sufficiently credible to plead a corrective disclosure”); *In re Eros Int’l PLC Sec. Litig.*, 2021 WL 1560728, at *15 (D.N.J. Apr. 20, 2021) (report corroborated by company’s disclosure of late loan payments)).

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that on January 23, 2023, a true and correct copy of this reply motion was served upon each attorney of record through the Court's CM/ECF system.

/s/ James N. Kramer
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